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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,105	09/21/2007	Kevin G. Pinney	BAYU-0002 WO/US	8911
25555 7590 02/19/2010 JACKSON WALKER LLP 901 MAIN STREET SUITE 6000 DALLAS, TX 75202-3797				
EXAMINER LEESER, ERICH A				
ART UNIT		PAPER NUMBER		
1624				
MAIL DATE		DELIVERY MODE		
02/19/2010		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/594,105

**Applicant(s)**

PINNEY ET AL.

**Examiner**

Erich A. Leeser

**Art Unit**

1624

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4, 11, 12, 14, 21 and 24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4, 11-12, 14, 21, and 24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This action is in response to Applicant's submission dated January 25, 2010, in which Applicant withdrew claims 1-3, 5-10, 15-20, and 22-23; amended claims 4, 11-12, and 14, and cancelled claim 13. Claims 4, 11-12, 14, 21, and 24 are pending and under examination.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 11-12, 14, 21, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- i) In the preamble, the claim term "serotonin reuptake inhibitor" is unclear because this term does not clearly set forth if a compound or composition is claimed. This rejection may be obviated by amending the preamble to recite "A compound", rather than the existing term in the preamble. Correction is required.
- ii) The term "aryl moiety" in claim 4 is unclear because one skilled in the art would not necessarily be able to determine the scope of this claim term. It appears that this term includes unsubstituted carbocyclic groups, for example, phenyl, naphthyl, etc. as well as substituted phenyl, etc. wherein the substituents can be any known substituent. The term is generally understood to cover unsaturated carbocyclic groups such as phenyl, naphthyl, etc. In addition, the proviso statements are excluding heteroaromatic groups such as benzo[d]isoxazole, pyrimidyl, pyridyl, etc. which tends to show that the term "aryl moiety" is intended to include

groups that are generally referred as "heteroaryl". Clarification is required as the term appears to extend beyond what is generally known to an ordinary artisan skilled in heterocyclic organic chemistry.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because it has been amended to recite several new matter "exclusionary" provisos. All claim limitations including negative limitations must find support in the specification as originally filed. To obviate this rejection, Applicant must show support for these newly added negative claim limitations. See MPEP 2173.05(h).

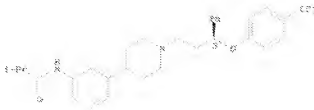
#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

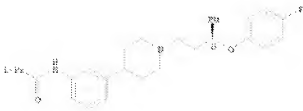
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4 and 21 are rejected under 35 USC 102(b) as being anticipated by Borowsky, et al., U.S. Patent No. 6,221,613. Borowsky, et al. teaches human melanin concentrating hormone receptor MCH1, its DNA, its synthetic ligands and diagnostic and therapeutic uses thereof. The reference teaches instant



compounds. Specifically, the compound of the reference anticipates the aforementioned claims wherein  $X = CF_3$ ,  $n = 1$ ,  $A = C$ , and Ar is an aryl moiety. In addition,



of the reference anticipates the aforementioned claims wherein  $X = F$ ,  $n = 1$ ,  $A = C$ , and Ar is an aryl moiety.

### ***Claim Rejections - 35 USC § 103***

1. Claims 4 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martinez-Esparza, et al., *New 1-aryl-3-(4-arylpiperazin-1-yl)propane derivatives, with dual action at 5-HT1A serotonin receptors and serotonin transporter, as a new class of antidepressants*, Journal of Medicinal Chemistry 44(3), 418-428 (2001).

Claim 4 excludes the compounds disclosed in the reference, see the proviso, that when  $n = 1$ , Ar is excluding 2-methoxyphenyl, etc. Claim 4, however, includes the full scope of compounds when  $X = CF_3$ ,  $n = 0$ , and  $A = N$  or  $C$ , meaning that no Ar groups are excluded in this situation. The reference teaches the same use for the compounds and therefore, the compounds having a  $-CH_2-$  linker instead of a  $-(CH_2)_2-$  linker would be obvious to one having ordinary skill in the art.

Applicant argues that, "... whereas the CH<sub>2</sub> groups in the currently claimed compounds appear to position the critical functional groups, as indicated by the variants ..." This argument is of speculative nature and there is no evidence to show the criticality of the methylene linker. As such, claim 4 continues to be a classic homolog issue and *Henze* is therefore still on point.

Therefore, Applicant could obviate this rejection by providing evidence demonstrating the criticality or unexpected superiority of the methylene linker.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 103 that form the basis for the rejections under this section made in this Office action:

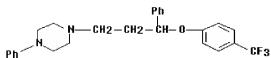
2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4 and 21 rejected under 35 USC 103(a) as being rendered obvious by Jakobsen, et al., EP 576766.

**Determining the scope and contents of the prior art.**

Jakobsen, et al. teaches the preparation of (hetero)arylpropanolamine derivatives as cerebral calcium overload blockers, very similar to instant compounds. Specifically, the compound 1-phenyl-4-[3-phenyl-3-[4-(trifluoromethyl)phenoxy]propyl]-ethanedioate piperazine with the following structure:



of the

reference renders the aforementioned claims obvious where A is N, Ar is unsubstituted, n is 1, and X is CF<sub>3</sub>. The references compounds exhibit the same activity as the compounds of the instant claims.

**Ascertaining the difference between the prior art and the claims at issue.**

Claim 4 excludes the compounds disclosed in the reference, see the proviso, that when n = 1, Ar is excluding 2-methoxyphenyl, etc. Claim 4, however, includes the full scope of compounds when X = CF<sub>3</sub>, n = 0, and A = N or C, meaning that no Ar groups are excluded in this situation. The reference teaches the same use for the compounds and therefore, the compounds excluded by the proviso would be obvious to one having ordinary skill in the art.

**Resolving the level of skill in the art.**

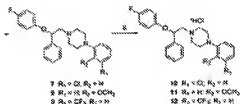
It would have required little more than routine modification of the synthesis of compounds of the reference by one having ordinary skill in this art at the time the invention was made to prepare a compound within the scope of the compounds instantly claimed as Applicant has done with the above-cited reference before them. The variants show the interchangeability of the overlapping substituents and the compounds of the prior art are prepared and used for the same purpose as those instantly claimed.

Claims 4 and 21 are rejected under 35 USC 103(a) as being rendered obvious by Dorsey, et al., *Synthesis and Biological Evaluation of 2-(4-fluorophenoxy)-2-phenyl-ethyl Piperazines as Serotonin-selective Reuptake Inhibitors with a Potentially Improved Adverse Reaction Profile*,

Bioorganic & Med. Chem., 12, 1483-91 (2004). An Internet search indicates that this reference published on March 15, 2004.

### Determining the scope and contents of the prior art.

Dorsey, et al. teaches 2-(4-fluorophenoxy)-2-phenyl-ethyl piperazines, which include instant



compounds. Specifically, the compounds of the reference render the aforementioned claims obvious where A is N, Ar is substituted with chloro, methoxy or  $CF_3$ , n is 0, and X is fluoro. The references compounds exhibit the same activity as the compounds of the instant claims.

### Ascertaining the difference between the prior art and the claims at issue.

Claim 4 excludes the compounds disclosed in the reference, see the proviso, that when n = 1, Ar is excluding 2-methoxyphenyl, etc. Claim 4, however, includes the full scope of compounds when  $X = CF_3$ , n = 0, and A = N or C, meaning that no Ar groups are excluded in this situation. The reference teaches the same use for the compounds and therefore, the compounds excluded by the proviso would be obvious to one having ordinary skill in the art.

### Resolving the level of skill in the art.

It would have required little more than routine modification of the synthesis of compounds of the reference by one having ordinary skill in this art at the time the invention was made to prepare a compound within the scope of the compounds instantly claimed as Applicant has done with the above-cited reference before them. The variants show the interchangeability



of the overlapping substituents and the compounds of the prior art are prepared and used for the same purpose as those instantly claimed.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Erich A. Leeser whose telephone number is 571-272-9932. The Examiner can normally be reached Monday through Friday from 8:30 to 6:00 EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. James O. Wilson can be reached at 571-272-0661. The fax number for the organization where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) toll-free at 866-217-9197. If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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